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GILEAD SCIENCES, INC.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

BRIAN EVANS,)	CIVIL NO. 20-00123 DKW-KJM
)	
Plaintiff,)	DEFENDANT GILEAD SCIENCES,
)	INC.'S REPLY IN SUPPORT OF
vs.)	MOTION TO DISMISS
)	COMPLAINT; CERTIFICATE OF
GILEAD SCIENCES, INC., et al.,)	SERVICE
)	
Defendant.)	
)	

DEFENDANT GILEAD SCIENCES, INC.'S REPLY
IN SUPPORT OF MOTION TO DISMISS COMPLAINT

I. INTRODUCTION

In his Opposition to Gilead's Motion to Dismiss [D.E. 31] ("Opposition" or "Opp."), Plaintiff does not address, much less refute, any of Gilead's bases for dismissal of Plaintiff's Amended Complaint. Instead, Plaintiff raises entirely new allegations that are irrelevant to his claims, improper for consideration in response to a motion to dismiss, and, in any event, insufficient to state a cause of action. Accordingly, for the reasons set forth in Gilead's Memorandum in Support of its Motion to Dismiss [D.E. 20-1] ("Memorandum" or "Mem.") and further below, Plaintiff's Amended Complaint should now be dismissed with prejudice.

II. ARGUMENT

As set forth in Gilead's Memorandum, Plaintiff's Amended Complaint should be dismissed on numerous grounds.

Plaintiff has not pled a cognizable design defect theory, because, contrary to his allegation that Gilead "refused to make [TAF medications] available" earlier, Gilead indisputably *did* make each of the TAF medications available before Plaintiff was ever prescribed Truvada[®]. Mem. at 10-11.¹ Plaintiff has not pled a

¹ Unless otherwise specified, defined terms have the same meanings given to them in Gilead's Memorandum.

cognizable failure to warn claim, because the FDA-approved labeling for Truvada[®] indisputably contained the warnings that Plaintiff erroneously alleges were missing, and Plaintiff has not pled any facts showing that any purportedly insufficient warnings caused his alleged injury. *Id.* at 11-15. Plaintiff has not pled his fraud claim in accordance with Rule 9(b), because he does not allege (a) any misrepresentations ever made to him or his doctor, (b) who made any such misrepresentations, (c) when, where, or how any purported misrepresentations were made, or (d) how he or his doctor relied on any alleged misrepresentations. *Id.* at 15-17. Plaintiff likewise does not plead any facts to support a breach of warranty claim, including the identification of any alleged warranty ever made to him or his doctor. *Id.* at 18-20.

Finally, each of Plaintiff's theories of liability—upon which all of his claims are based—are preempted by federal law: Federal law preempts his design defect theory because Gilead could not have marked the TAF medications—as Plaintiff seeks to demand—without prior FDA approval. Plaintiff's failure to warn theory is likewise preempted because Plaintiff cannot use state law to challenge warnings contained in the FDA-approved original labeling for Truvada[®], and Plaintiff has not alleged any “newly acquired information” that would have permitted Gilead to unilaterally change the Truvada[®] labeling after FDA approval. *Id.* at 20-31.

Plaintiff's Opposition to Gilead's Motion to Dismiss [D.E. 31]

("Opposition" or "Opp.") does not even *mention*, let alone *contest*, any of these bases for dismissal of his Amended Complaint. Because Plaintiff fails to refute any of these grounds for dismissal, his Amended Complaint should be dismissed for the reasons set forth in Gilead's Memorandum.

Plaintiff's Opposition consists almost exclusively of new allegations that are raised for the first time in his Opposition and irrelevant to his product liability claims. However, "facts that were not in [plaintiff's complaint] but were alleged in [his] opposition to the Rule 12(b)(6) dismissal motion[]" are not properly considered in ruling on a motion to dismiss. *Broam v. Bogan*, 320 F.3d 1023, 1026 n.2 (9th Cir. 2003); *id.* ("In determining the propriety of a Rule 12(b)(6) dismissal, a court *may not* look beyond the complaint to a plaintiff's moving papers, such as a memorandum in opposition to a defendant's motion to dismiss.") (quoting *Schneider v. Cal. Dep't of Corrections*, 151 F.3d 1194, 1197 n.1 (9th Cir. 1998)). Because none of the new allegations raised for the first time in Plaintiff's Opposition may be considered in determining whether he has stated a viable cause of action, they cannot save his claims from dismissal.

Nor do Plaintiff's new allegations provide a basis for granting him leave to amend his Complaint. *See id.* ("Facts raised for the first time in plaintiff's

opposition papers should be considered by the court in determining whether to grant leave to amend or dismiss the complaint with or without prejudice.”).

Plaintiff’s Opposition appears to consist almost entirely of allegations copied from the complaint in an *antitrust* case filed against Gilead. *Compare* Opp. ¶¶ 1-14, with *Staley, et al. v. Gilead Sciences, Inc., et al.*, No. 3:19-cv-02573 (N.D. Cal.), Class Action Complaint [D.E. 1] ¶¶ 1-14. Plaintiff’s Opposition, however, does not express an intent to actually assert an antitrust claim (as opposed to Plaintiff’s asserted product liability claims), nor does it state a plausible antitrust claim.

For instance, Plaintiff has not alleged any “antitrust injury.” *See, e.g., Pool Water Prods. v. Olin Corp.*, 258 F.3d 1024, 1034 (9th Cir. 2001) (“[P]rivate plaintiffs [asserting antitrust claims] can be compensated only for injuries that the antitrust laws were intended to prevent.”). “An ‘antitrust injury’ is an injury of ‘the type that the antitrust statute was intended to forestall,’” *i.e.*, “‘injury from higher prices or lower output, the principal vices proscribed by the antitrust laws.’” *Id.* (quoting *Associated Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 540 (1983); *Nelson v. Monroe Regional Med. Ctr.*, 925 F.2d 1555, 1564 (7th Cir. 1991)). Although Plaintiff’s Opposition (unlike his Amended Complaint) asserts that Gilead obtained “inflated profits” from purportedly anticompetitive behavior, Opp. at 4, he only allegedly suffered a personal injury (diffuse arthralgia) based on a purported design defect and failure to warn of risks associated with Truvada®.

Am. Compl. [D.E. 8] at 2; *see also* Opp. at 9-10 (alleging the “impact on the plaintiff in this case”). This plainly is not an “antitrust injury” for which Plaintiff could assert an antitrust cause of action. *See, e.g., Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990) (“injury, although causally related to an antitrust violation, nevertheless will not qualify as ‘antitrust injury’ unless it is attributable to an anti-competitive aspect of the practice under scrutiny”); *In re Libor-Based Fin. Instruments Antitrust Litig.*, No. 11 MDL 2262, 2015 WL 4634541, at *83 (S.D.N.Y. Aug. 4, 2015) (“[T]his is plainly not an antitrust injury, because physical injury is the kind of injury that commonly and directly follows from a defective product design, regardless of whether an antitrust conspiracy somehow enabled the design defect in a particular case.”).

III. CONCLUSION

For the foregoing reasons, and those set forth in Gilead’s Memorandum, Plaintiff’s Amended Complaint should be dismissed with prejudice. Plaintiff has not addressed any of Gilead’s grounds for dismissal of his Amended Complaint, the irrelevant allegations set forth for the first time in his Opposition should not be considered in addressing Gilead’s Motion to Dismiss, and in any event, the additional allegations in Plaintiff’s Opposition do not state a cause of action.

DATED: Honolulu, Hawaii, July 15, 2020.

/s/ Stefan M. Reinke

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ALYCIA A. DEGEN

Attorneys for Defendant

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BRIAN EVANS,)	CIVIL NO. 20-00123 DKW-KJM
)	
Plaintiff,)	CERTIFICATE OF SERVICE
)	
vs.)	
)	
GILEAD SCIENCES, INC., et al.,)	
)	
Defendant.)	
_____)	

CERTIFICATE OF SERVICE

I hereby certify that on this date, a true and correct copy of the foregoing document was duly served on the following party in the manner indicated below:

	<u>E-MAIL</u>	<u>MAIL</u>
BRIAN EVANS belasvegas@yahoo.com 160 Keonekai Road, Unit 25-104 Kihei, Hawaii 96753 Plaintiff	<u>X</u>	<u>X</u>

DATED: Honolulu, Hawaii, July 15, 2020.

/s/ Stefan M. Reinke
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